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PATENT COOPERATION TREATY

PCT

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

GORDON Stark
Murgitroyd & Company
373 Scotland Street
Glasgow, G5 8QA
ROYAUME-UNI

Date of mailing (day/month/year) 15 October 2001 (15.10.01)		IMPORTANT NOTIFICATION	
Applicant's or agent's file reference P2660PC/TIPD			
International application No. PCT/GB00/03228		International filing date (day/month/year) 18 August 2000 (18.08.00)	
1. The following indications appeared on record concerning: <input type="checkbox"/> the applicant <input type="checkbox"/> the inventor <input checked="" type="checkbox"/> the agent <input type="checkbox"/> the common representative			
Name and Address DUMMETT, Thomas, Ian, Peter Dummett Copp 25 The Square Martlesham Heath Ipswich IP5 3SL United Kingdom		State of Nationality	State of Residence
		Telephone No. 01473 660600	
		Facsimile No. 01473 660612	
		Teleprinter No.	
2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning: <input checked="" type="checkbox"/> the person <input checked="" type="checkbox"/> the name <input checked="" type="checkbox"/> the address <input type="checkbox"/> the nationality <input type="checkbox"/> the residence			
Name and Address GORDON Stark Murgitroyd & Company 373 Scotland Street Glasgow, G5 8QA United Kingdom		State of Nationality	State of Residence
		Telephone No. 44(0)141 307 8400	
		Facsimile No. 44(0)141 307 8401	
		Teleprinter No.	
3. Further observations, if necessary:			
4. A copy of this notification has been sent to: <input checked="" type="checkbox"/> the receiving Office <input type="checkbox"/> the designated Offices concerned <input type="checkbox"/> the International Searching Authority <input checked="" type="checkbox"/> the elected Offices concerned <input checked="" type="checkbox"/> the International Preliminary Examining Authority <input type="checkbox"/> other:			
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35		Authorized officer Ki-Nam HA Telephone No.: (41-22) 338.83.38	

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE
in its capacity as elected Office

Date of mailing (day/month/year) 18 June 2001 (18.06.01)	
International application No. PCT/GB00/03228	Applicant's or agent's file reference P2660PC/TIPD
International filing date (day/month/year) 18 August 2000 (18.08.00)	Priority date (day/month/year) 19 August 1999 (19.08.99)
Applicant COLACO, Camilo, Anthony, Leo, Selwyn	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
13 March 2001 (13.03.01)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Olivia TEFY Telephone No.: (41-22) 338.83.38
---	---

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
1 March 2001 (01.03.2001)

PCT

(10) International Publication Number
WO 01/13944 A2

(51) International Patent Classification?: **A61K 39/00**

(21) International Application Number: **PCT/GB00/03228**

(22) International Filing Date: **18 August 2000 (18.08.2000)**

(25) Filing Language: **English**

(26) Publication Language: **English**

(30) Priority Data: **9919734.5** **19 August 1999 (19.08.1999)** **GB**

(71) Applicant (for all designated States except US): **IM-MUNOBIOLOGY LIMITED [GB/GB];** Babraham Bioincubators, Babraham, Cambridge CB2 4AT (GB).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **COLACO, Camilo, Anthony, Leo, Selwyn [GB/GB];** 107 Foster Road, Cambridge CB2 2JN (GB).

(74) Agents: **DUMMETT, Thomas, Ian, Peter et al.;** Dummett Copp, 25 The Square, Martlesham Heath, Ipswich IP5 3SL (GB).

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

— Without international search report and to be republished upon receipt of that report.

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 01/13944 A2

(54) Title: **VACCINES FROM INFECTIOUS AGENTS**

(57) Abstract: The present invention relates to a method for producing and isolating specific immunogenic endogenous heat shock proteins induced by the treatment of extra-cellular pathogens with stress inducing stimuli and vaccines prepared from such proteins.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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International Bureau



(43) International Publication Date
1 March 2001 (01.03.2001)

PCT

(10) International Publication Number
WO 01/13944 A3

- (51) International Patent Classification⁷: **A61K 39/00**, 39/002, 39/02, A61P 31/04, 31/10, 33/02
- (21) International Application Number: **PCT/GB00/03228**
- (22) International Filing Date: 18 August 2000 (18.08.2000)
- (25) Filing Language: English
- (26) Publication Language: English
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9919734.5 19 August 1999 (19.08.1999) GB
- (71) Applicant (for all designated States except US): **IMMUNOBIOLOGY LIMITED [GB/GB]**; Babraham Biocubators, Babraham, Cambridge CB2 4AT (GB).
- (72) Inventor; and
- (75) Inventor/Applicant (for US only): **COLACO, Camilo, Anthony, Leo, Selwyn [GB/GB]**; 107 Foster Road, Cambridge CB2 2JN (GB).
- (74) Agents: **DUMMETT, Thomas, Ian, Peter et al.**; Dummett Copp, 25 The Square, Martlesham Heath, Ipswich IP5 3SL (GB).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
- Published:
— with international search report
- (88) Date of publication of the international search report:
20 September 2001
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 01/13944 A3

(54) Title: **STRESS-PROTEINS FROM EXTRA-CELLULAR PATHOGENS AS VACCINES AGAINST INFECTIOUS AGENTS**

(57) Abstract: The present invention relates to a method for producing and isolating specific immunogenic endogenous heat shock proteins induced by the treatment of extra-cellular pathogens with stress inducing stimuli and vaccines prepared from such proteins.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 00/03228

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K39/00 A61K39/002 A61K39/02 A61P31/04 A61P31/10
A61P33/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

MEDLINE, LIFESCIENCES, CANCERLIT, CHEM ABS Data, SCISEARCH, BIOSIS, WPI Data, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 90 02564 A (CODON) 22 March 1990 (1990-03-22) page 2, line 24 -page 3, line 28 example 2J example 3F	11-17
A	---	1-10
X	WO 96 40928 A (HAMEL JOSEE ;RIOUX CLEMENT (CA); BRODEUR BERNARD (CA); IAF BIOVAC) 19 December 1996 (1996-12-19) page 6, line 37 -page 7, line 14 examples 5,7,10 --- -/--	11-17

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

A document member of the same patent family

Date of the actual completion of the international search

16 February 2001

Date of mailing of the international search report

01/03/2001

Name and mailing address of the ISA

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NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Covone, M

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 00/03228

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		Relevant to claim No.
Category *	Citation of document, with indication, where appropriate, of the relevant passages	
X	<p>FERRERO RICHARD L ET AL: "The GroES homolog of Helicobacter pylori confers protective immunity against mucosal infection in mice."</p> <p>PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF THE UNITED STATES, vol. 92, no. 14, 1995, pages 6499-6503, XP002160650</p> <p>1995</p> <p>ISSN: 0027-8424</p> <p>the whole document -----</p>	11-17

INTERNATIONAL SEARCH REPORT

information on patent family members

International Application No

PCT/GB 00/03228

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9002564 A	22-03-1990	NONE	
WO 9640928 A	19-12-1996	US 5919620 A	06-07-1999
		AU 700080 B	17-12-1998
		AU 5682896 A	30-12-1996
		CA 2224015 A	19-12-1996
		CN 1192241 A	02-09-1998
		CZ 9703942 A	15-04-1998
		EP 0832238 A	01-04-1998
		JP 11507214 T	29-06-1999
		NO 975752 A	06-02-1998
		PL 323781 A	27-04-1998
		SK 168497 A	08-07-1998
		TR 9701537 T	21-03-1998

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

MURGITROYD & COMPANY
Chartered Patent Agents
373 Scotland Street
Glasgow G5 8QA
GRANDE BRETAGNE

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing
(day/month/year) 03.12.2001

Applicant's or agent's file reference
P28669

IMPORTANT NOTIFICATION

International application No.
PCT/GB00/03228

International filing date (day/month/year)
18/06/2000

Priority date (day/month/year)
19/08/1999

Applicant
IMMUNOBIOLOGY LIMITED et al

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER:

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/



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From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

MURGITROYD & COMPANY
Chartered Patent Agents
373 Scotland Street
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GRANDE BRETAGNE

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing
(day/month/year) 03.12.2001

Applicant's or agent's file reference
P28669

IMPORTANT NOTIFICATION

International application No.
PCT/GB00/03228

International filing date (day/month/year)
18/06/2000

Priority date (day/month/year)
19/08/1999

Applicant
IMMUNOBIOLOGY LIMITED et al

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
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Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/



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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P28669		FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB00/03228	International filing date (day/month/year) 18/08/2000	Priority date (day/month/year) 19/08/1999		
International Patent Classification (IPC) or national classification and IPC AG1K39/00				
Applicant IMMUNOBIOLOGY LIMITED et al				
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 3 sheets.</p>				
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input checked="" type="checkbox"/> Certain observations on the international application</p>				
Date of submission of the demand 13/03/2001		Date of completion of this report 03.12.2001		
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523655 epmu Fax: +49 89 2399 - 4485		Authorized officer Renggli, J Telephone No. +49 89 2399 7461		



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**International application No. **PCT/GB00/03228****I. Basis of the report**

1. With regard to the elements of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-16 as originally filed

Claims, No.:

1-15 with telefax of 21/11/2001

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/03228

(Any replacement sheet containing such amendments must be referred to under Item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 14,15 with respect to industrial applicability.

because:

☒ the said international application, or the said claims Nos. 14,15 with respect to industrial applicability relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
- ☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	8,15
	No:	Claims	1-7,9-14
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-15
Industrial applicability (IA)	Yes:	Claims	1-13

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/03228

No: Claims

2. Citations and explanations
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

INTERNATIONAL PRELIMINARY

International application No. PCT/GB00/03228

EXAMINATION REPORT - SEPARATE SHEET

ITEM III:

Claims 14 and 15 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67 1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

ITEM V:

1. Reference is made to the following document:

D1 WO 95/40928

2. Industrial applicability (Art. 33(4) PCT):

The subject-matter of claims 1-13 is susceptible of industrial application.

For the assessment of the present claims 14 and 15 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

3. Novelty (Art. 33(2) PCT):

D1, which is considered to be the closest prior art, discloses heat-shock proteins (hsp) of the extracellular pathogens *S. pneumoniae*, *S. pyogenes* and *S. agalactiae* (see page 6, line 36-page 7, line 14). These proteins, which are naturally occurring protein that exhibits preferential transcription during heat stress conditions, may be used as vaccines against the said pathogens and may be obtained by recombinant expression or may be of natural origin, i.e. extracted after heat treatment at 45° C (see page 15, lines 20-33; page 20, lines 13-21; page 34, line 35-page 36, line 5; example 10).

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/03228

At this stage, it should be noted that the procedure used in document D1 for preparing the heat-induced immunogens (see D1, example 1, pages 34-39) is in many respects similar to the procedure disclosed in the present application. It is thus considered that the procedure used in D1 would also (**inherently**) lead to the isolation of stress protein/antigenic peptide fragment complexes. As to the type of immune responses measured in D1, it is respectfully submitted that the fact that the said measurements were limited to hsp in D1 does not prove that complexes as defined in the present application (see examples 3 and 4 of the present application) were absent from the preparation of D1.

Moreover, it should be noted that claim 1 is not limited to the use of the said complexes for producing a vaccine but encompasses the use of stress induced products. This fact is also clear in view of claim 2 which indicates that other components are present in the active ingredient, due to the use of the wording "consists predominantly".

Consequently, D1 which clearly contemplates the use of the products disclosed in example 1 for the production of a vaccine (see D1, page 15, lines 23-33) is considered to be prejudicial to the novelty of claims 1-7 and 9-14 of the present application.

4. Inventive step (Art. 33(3) PCT):

Claim 8 does not appear to solve a technical problem in an unexpected way over D1 and is therefore not regarded as inventive. All the modifications proposed lie within the standard abilities of the skilled person.

Applying the teaching of D1 to intracellular pathogens is a straightforward modification which does not involve an inventive step (see claim 15).

Claims 8 and 15 are thus not inventive within the meaning of Article 33(3) PCT.

ITEM VIII:

Claim 9 would appear to be superfluous. It is not clear how the method of claim 1 could be carried out in vivo; moreover, this has not been shown in the present application which is limited to in vitro methods.

1 CLAIMS

2
3 1. A method for producing a vaccine containing an
4 immunogenic determinant, comprising the steps of:
5 exposing extra-cellular pathogenic organisms to
6 stress-inducing stimuli which would induce the
7 production of stress protein/antigenic peptide
8 fragment complexes;
9 extracting the endogenous stress-induced
10 products from the treated organisms;
11 and using the extracted products as the
12 immunogenic determinant in the preparation of the
13 vaccine composition.

14
15 2. A method as claimed in claim 1, characterised
16 in that the active ingredient of the immunogenic
17 determinant consists predominantly of one or more
18 shock protein/antigenic peptide fragment complexes.

19
20 3. A method as claimed in either of claims 1 or 2,
21 characterised in that the stress-inducing stimulus
22 is heat.

23
24 4. A method as claimed in claim 3, characterised
25 in that the pathogenic organism is heated to from 5
26 to 8°C above the normal temperature for cultivation
27 of the organism.

28
29 5. A method as claimed in any of one of the
30 preceding claims, characterised in that the
31 pathogenic organism is an extra-cellular procaryotic
32 or protozoan species.

- 1 6. A method as claimed in any one of the preceding
2 claims, characterised in that the pathogenic
3 organism is a bacterial, protozoal or fungal
4 species.
5
- 6 7. A method as claimed in any one of the preceding
7 claims, characterised in that the immunogenic
8 determinant is a mixture of heat shock
9 protein/antigenic peptide fragment complexes.
10
- 11 8. A method as claimed in any one of the preceding
12 claims, characterised in that the extra-cellular
13 pathogenic organism has been modified to induce or
14 enhance the induction of the synthesis of stress
15 proteins.
16
- 17 9. A method as claimed in any one of the preceding
18 claims, characterised in that it is carried out in
19 vitro.
20
- 21 10. A vaccine composition containing an immunogenic
22 determinant, characterised in that the immunogenic
23 determinant comprises one or more complexes between
24 a heat shock protein and an antigenic peptide
25 fragment derived from the heat treatment of an
26 extra-cellular pathogenic organism.
27
- 28 11. A vaccine composition produced by the method of
29 any one of claims 1 to 9.
30
- 31 12. A vaccine composition as claimed in either of
32 claims 10 or 11, characterised in that the

1 composition also contains an adjuvant for the
2 immunogenic determinant.

3

4 13. A vaccine composition as claimed in any one of
5 claims 10 to 12, characterised in that it is an
6 aqueous composition.

7

8 14. A method for treating an animal with a vaccine,
9 characterised in that it comprises administering a
10 pharmaceutically acceptable quantity of a vaccine
11 composition as claimed in any one of claims 10 to 13
12 sufficient to elicit an immune response in the
13 animal.

14

15 15. A method for eliciting an immune response from
16 an animal to infection by an intra-cellular
17 pathogenic organism the method comprising the steps
18 of;

19 administering a vaccine containing an
20 immunogenic determinant, the immunogenic determinant
21 being a stress protein/antigenic peptide fragment
22 complex produced in situ from the intra-cellular
23 pathogen, the synthesis of the complex being induced
24 by external stress stimuli or by genetic
25 modification of the pathogen so as to render its
26 synthesis constitutive.

1 CLAIMS

2

3 1. A method for producing a vaccine containing an
4 immunogenic determinant, comprising the steps of:
5 exposing extra-cellular pathogenic organisms to
6 stress-inducing stimuli which would induce the
7 production of stress protein/antigenic peptide
8 fragment complexes;
9 extracting the endogenous stress-induced
10 products from the treated organisms;
11 and using the extracted products as the
12 immunogenic determinant in the preparation of the
13 vaccine composition.

14

15 2. A method as claimed in claim 1, characterised
16 in that the active ingredient of the immunogenic
17 determinant consists predominantly of one or more
18 shock protein/antigenic peptide fragment complexes.

19

20 3. A method as claimed in either of claims 1 or 2,
21 characterised in that the stress-inducing stimulus
22 is heat.

23

24 4. A method as claimed in claim 3, characterised
25 in that the pathogenic organism is heated to from 5
26 to 8°C above the normal temperature for cultivation
27 of the organism.

28

29 5. A method as claimed in any of one of the
30 preceding claims, characterised in that the
31 pathogenic organism is an extra-cellular procaryotic
32 or protozoan species.

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AD

1 6. A method as claimed in any one of the preceding
2 claims, characterised in that the pathogenic
3 organism is a bacterial, protozoal or fungal
4 species.

5
6 7. A method as claimed in any one of the preceding
7 claims, characterised in that the immunogenic
8 determinant is a mixture of heat shock
9 protein/antigenic peptide fragment complexes.

10
11 8. A method as claimed in any one of the preceding
12 claims, characterised in that the extra-cellular
13 pathogenic organism has been modified to induce or
14 enhance the induction of the synthesis of stress
15 proteins.

16
17 9. A method as claimed in any one of the preceding
18 claims, characterised in that it is carried out in
19 vitro.

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21 10. A vaccine composition containing an immunogenic
22 determinant, characterised in that the immunogenic
23 determinant comprises one or more complexes between
24 a heat shock protein and an antigenic peptide
25 fragment derived from the heat treatment of an
26 extra-cellular pathogenic organism.

27
28 11. A vaccine composition produced by the method of
29 any one of claims 1 to 9.

30
31 12. A vaccine composition as claimed in either of
32 claims 10 or 11, characterised in that the

1 composition also contains an adjuvant for the
2 immunogenic determinant.

3
4 13. A vaccine composition as claimed in any one of
5 claims 10 to 12, characterised in that it is an
6 aqueous composition.

7
8 14. A method for treating an animal with a vaccine,
9 characterised in that it comprises administering a
10 pharmaceutically acceptable quantity of a vaccine
11 composition as claimed in any one of claims 10 to 13
12 sufficient to elicit an immune response in the
13 animal.

14
15 15. A method for eliciting an immune response from
16 an animal to infection by an intra-cellular
17 pathogenic organism the method comprising the steps
18 of;
19 administering a vaccine containing an
20 immunogenic determinant, the immunogenic determinant
21 being a stress protein/antigenic peptide fragment
22 complex produced in situ from the intra-cellular
23 pathogen, the synthesis of the complex being induced
24 by external stress stimuli or by genetic
25 modification of the pathogen so as to render its
26 synthesis constitutive.

REPLACED BY
ART 34 AMADT

PATENT COOPERATION TREATY

PCT

REC'D 06 DEC 2001

WIPO

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P28669	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB00/03228	International filing date (day/month/year) 18/08/2000	Priority date (day/month/year) 19/08/1999
International Patent Classification (IPC) or national classification and IPC A61K39/00		
Applicant IMMUNOBIOLOGY LIMITED et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 13/03/2001	Date of completion of this report 03.12.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Renggli, J Telephone No. +49 89 2399 7461 

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/03228

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):
Description, pages:

1-16 as originally filed

Claims, No.:

1-15 with telefax of 21/11/2001

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
 - ☐ the language of publication of the international application (under Rule 48.3(b)).
 - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- ☐ contained in the international application in written form.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority in written form.
 - ☐ furnished subsequently to this Authority in computer readable form.
 - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
 - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.
4. The amendments have resulted in the cancellation of:
- ☐ the description, pages:
 - ☐ the claims, Nos.:
 - ☐ the drawings, sheets:
5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/03228

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 14,15 with respect to industrial applicability.

because:

- ☒ the said international application, or the said claims Nos. 14,15 with respect to industrial applicability relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet
 - ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
 - ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
 - ☐ no international search report has been established for the said claims Nos. .
2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:
- ☐ the written form has not been furnished or does not comply with the standard.
 - ☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims 8,15
	No: Claims 1-7,9-14
Inventive step (IS)	Yes: Claims
	No: Claims 1-15
Industrial applicability (IA)	Yes: Claims 1-13

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/03228

No: Claims

2. Citations and explanations
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

ITEM III:

Claims 14 and 15 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

ITEM V:

1. Reference is made to the following document:

D1 WO 96/40928

2. Industrial applicability (Art. 33(4) PCT):

The subject-matter of claims 1-13 is susceptible of industrial application.

For the assessment of the present claims 14 and 15 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

3. Novelty (Art. 33(2) PCT):

D1, which is considered to be the closest prior art, discloses heat-shock proteins (hsp) of the extracellular pathogens *S. pneumoniae*, *S. pyogenes* and *S. agalactiae* (see page 6, line 36-page 7, line 14). These proteins, which are naturally occurring protein that exhibits preferential transcription during heat stress conditions, may be used as vaccines against the said pathogens and may be obtained by recombinant expression or may be of natural origin, i.e. extracted after heat treatment at 45° C (see page 15, lines 20-33; page 20, lines 13-21; page 34, line 35-page 36, line 5; example 10).

At this stage, it should be noted that the procedure used in document D1 for preparing the heat-induced immunogens (see D1, example 1, pages 34-39) is in many respects similar to the procedure disclosed in the present application. It is thus considered that the procedure used in D1 would also (**inherently**) lead to the isolation of stress protein/antigenic peptide fragment complexes. As to the type of immune responses measured in D1, it is respectfully submitted that the fact that the said measurements were limited to hsp in D1 does not prove that complexes as defined in the present application (see examples 3 and 4 of the present application) were absent from the preparation of D1.

Moreover, it should be noted that claim 1 is not limited to the use of the said complexes for producing a vaccine but encompasses the use of stress induced products. This fact is also clear in view of claim 2 which indicates that other components are present in the active ingredient, due to the use of the wording "consists predominantly".

Consequently, D1 which clearly contemplates the use of the products disclosed in example 1 for the production of a vaccine (see D1, page 15, lines 23-33) is considered to be prejudicial to the novelty of claims 1-7 and 9-14 of the present application.

4. Inventive step (Art. 33(3) PCT):

Claim 8 does not appear to solve a technical problem in an unexpected way over D1 and is therefore not regarded as inventive. All the modifications proposed lie within the standard abilities of the skilled person.

Applying the teaching of D1 to intracellular pathogens is a straightforward modification which does not involve an inventive step (see claim 15).

Claims 8 and 15 are thus not inventive within the meaning of Article 33(3) PCT.

ITEM VIII:

Claim 9 would appear to be superfluous. It is not clear how the method of claim 1 could be carried out in vivo; moreover, this has not been shown in the present application which is limited to in vitro methods.

CLAIMS

1. A method for producing a vaccine containing an immunogenic determinant, comprising the steps of:
 - 5 a) exposing extra-cellular pathogenic organisms to stress-inducing stimuli which would induce the production of SP/antigenic peptide fragment complexes;
 - b) extracting the endogenous stress-induced products from the treated organisms; and
 - 10 c) using the extracted products as the immunogenic determinant in the preparation of the vaccine composition.
- 15 2. A method as claimed in claim 1, characterised in that the active ingredient of the immunogenic determinant consists predominantly of one or more shock protein/antigenic peptide fragment complexes.
- 20 3. A method as claimed in either of claims 1 or 2, characterised in that the stress-inducing stimulus is heat.
- 25 4. A method as claimed in claim 3, characterised in that the pathogenic organism is heated to from 5 to 8°C above the normal temperature for cultivation of the organisation.
- 30 5. A method as claimed in any one of the preceding claims, characterised in that the pathogenic organism is an extra-cellular procaryotic or protozoan

species.

- 5 6. A method as claimed in any one of the preceding claims, characterised in that the pathogenic organism is a bacterial, protozoal or fungal species.
- 10 7. A method as claimed in any one of the preceding claims, characterised in that the immunogenic determinant is a mixture of heat shock protein/antigenic peptide fragment complexes.
- 15 8. A method as claimed in any one of the preceding claims, characterised in that the extra-cellular pathogenic organism has been modified to induce or enhance the induction of the synthesis of stress proteins.
- 20 9. A method as claimed in any one of the preceding claims, characterised in that it is carried out in vitro.
- 25 10.A method as claimed in claim 1, substantially as hereinbefore described in any one of the Examples.
- 30 11.A vaccine composition containing an immunogenic determinant, characterised in that the immunogenic determinant comprises one or more complexes between a heat shock protein and an antigenic peptide fragment derived from the heat treatment of an extra-cellular pathogenic organisation.

- 12.A vaccine composition produced by the method of any one of claims 1 to 10.
- 5 13.A vaccine composition as claimed in either of claims 11 or 12, characterised in that the composition also contains an adjuvant for the immunogenic determinant.
- 10 14.A vaccine composition as claimed in any one of claims 11 to 13, characterised in that it is an aqueous composition.
- 15 15.A vaccine composition as claimed in any one of claims 11 to 14 substantially as hereinbefore described in any one of the Examples.
- 20 16.A method for treating an animal with a vaccine, characterised in that it comprises administering a pharmaceutically acceptable quantity of a vaccine composition as claimed in any one of claims 11 to 15 sufficient to elicit an immune response in the animal.
- 25 17. A method for eliciting an immune response from an animal to infection by an intra-cellular pathogenic organism which method comprises administering a vaccine containing an immunogenic determinant, characterised in that the immunogenic determinant is an SP/antigenic peptide fragment complex produced in situ from the intra-cellular pathogen whose synthesis is induced by external stress stimuli or by genetic
- 30

modification of the pathogen so as to render its
synthesis constitutive.

VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS

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REC'D 2 5 MAY 2001

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INTERNATIONALER VORLÄUFIGER PRÜFUNGSBERICHT

(Artikel 36 und Regel 70 PCT)

Aktenzeichen des Anmelders oder Anwalts 0050/049916	WEITERES VORGEHEN siehe Mitteilung über die Übersendung des internationalen vorläufigen Prüfungsberichts (Formblatt PCT/IPEA/416)	
Internationales Aktenzeichen PCT/EP00/03228	Internationales Anmeldedatum (Tag/Monat/Jahr) 11/04/2000	Prioritätsdatum (Tag/Monat/Tag) 20/04/1999
Internationale Patentklassifikation (IPK) oder nationale Klassifikation und IPK C08G67/02		
Anmelder BASF AKTIENGESELLSCHAFT et al.		



- Dieser internationale vorläufige Prüfungsbericht wurde von der mit der internationalen vorläufigen Prüfung beauftragten Behörde erstellt und wird dem Anmelder gemäß Artikel 36 übermittelt.
- Dieser BERICHT umfaßt insgesamt 4 Blätter einschließlich dieses Deckblatts.

☐ Außerdem liegen dem Bericht ANLAGEN bei; dabei handelt es sich um Blätter mit Beschreibungen, Ansprüchen und/oder Zeichnungen, die geändert wurden und diesem Bericht zugrunde liegen, und/oder Blätter mit vor dieser Behörde vorgenommenen Berichtigungen (siehe Regel 70.16 und Abschnitt 607 der Verwaltungsrichtlinien zum PCT).

 Diese Anlagen umfassen insgesamt Blätter.

3. Dieser Bericht enthält Angaben zu folgenden Punkten:

- I ☒ Grundlage des Berichts
- II ☐ Priorität
- III ☐ Keine Erstellung eines Gutachtens über Neuheit, erfinderische Tätigkeit und gewerbliche Anwendbarkeit
- IV ☐ Mangelnde Einheitlichkeit der Erfindung
- V ☒ Begründete Feststellung nach Artikel 35(2) hinsichtlich der Neuheit, der erfinderischen Tätigkeit und der gewerblichen Anwendbarkeit; Unterlagen und Erklärungen zur Stützung dieser Feststellung
- VI ☒ Bestimmte angeführte Unterlagen
- VII ☐ Bestimmte Mängel der internationalen Anmeldung
- VIII ☒ Bestimmte Bemerkungen zur internationalen Anmeldung

Datum der Einreichung des Antrags 02/09/2000	Datum der Fertigstellung dieses Berichts 10.05.2001
Name und Postanschrift der mit der internationalen vorläufigen Prüfung beauftragten Behörde:  Europäisches Patentamt D-80298 München Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Bevollmächtigter Bediensteter Andriollo, G Tel. Nr. +49 89 2399 8301 

I. Grundlage des Berichts

1. Hinsichtlich der **Bestandteile** der internationalen Anmeldung (*Ersatzblätter, die dem Anmeldeamt auf eine Aufforderung nach Artikel 14 hin vorgelegt wurden, gelten im Rahmen dieses Berichts als "ursprünglich eingereicht" und sind ihm nicht beigelegt, weil sie keine Änderungen enthalten (Regeln 70.16 und 70.17)*):
Beschreibung, Seiten:

1-28 ursprüngliche Fassung

Patentansprüche, Nr.:

1-10 ursprüngliche Fassung

2. Hinsichtlich der **Sprache**: Alle vorstehend genannten Bestandteile standen der Behörde in der Sprache, in der die internationale Anmeldung eingereicht worden ist, zur Verfügung oder wurden in dieser eingereicht, sofern unter diesem Punkt nichts anderes angegeben ist.

Die Bestandteile standen der Behörde in der Sprache: zur Verfügung bzw. wurden in dieser Sprache eingereicht; dabei handelt es sich um

- ☐ die Sprache der Übersetzung, die für die Zwecke der internationalen Recherche eingereicht worden ist (nach Regel 23.1(b)).
- ☐ die Veröffentlichungssprache der internationalen Anmeldung (nach Regel 48.3(b)).
- ☐ die Sprache der Übersetzung, die für die Zwecke der internationalen vorläufigen Prüfung eingereicht worden ist (nach Regel 55.2 und/oder 55.3).

3. Hinsichtlich der in der internationalen Anmeldung offenbarten **Nucleotid- und/oder Aminosäuresequenz** ist die internationale vorläufige Prüfung auf der Grundlage des Sequenzprotokolls durchgeführt worden, das:

- ☐ in der internationalen Anmeldung in schriftlicher Form enthalten ist.
- ☐ zusammen mit der internationalen Anmeldung in computerlesbarer Form eingereicht worden ist.
- ☐ bei der Behörde nachträglich in schriftlicher Form eingereicht worden ist.
- ☐ bei der Behörde nachträglich in computerlesbarer Form eingereicht worden ist.
- ☐ Die Erklärung, daß das nachträglich eingereichte schriftliche Sequenzprotokoll nicht über den Offenbarungsgehalt der internationalen Anmeldung im Anmeldezeitpunkt hinausgeht, wurde vorgelegt.
- ☐ Die Erklärung, daß die in computerlesbarer Form erfassten Informationen dem schriftlichen Sequenzprotokoll entsprechen, wurde vorgelegt.

4. Aufgrund der Änderungen sind folgende Unterlagen fortgefallen:

- ☐ Beschreibung, Seiten:
- ☐ Ansprüche, Nr.:
- ☐ Zeichnungen, Blatt:

5. ☐ Dieser Bericht ist ohne Berücksichtigung (von einigen) der Änderungen erstellt worden, da diese aus den angegebenen Gründen nach Auffassung der Behörde über den Offenbarungsgehalt in der ursprünglich eingereichten Fassung hinausgehen (Regel 70.2(c)).

(Auf Ersatzblätter, die solche Änderungen enthalten, ist unter Punkt 1 hinzuweisen; sie sind diesem Bericht beizufügen).

6. Etwaige zusätzliche Bemerkungen:

V. Begründete Feststellung nach Artikel 35(2) hinsichtlich der Neuheit, der erfinderischen Tätigkeit und der gewerblichen Anwendbarkeit; Unterlagen und Erklärungen zur Stützung dieser Feststellung

1. Feststellung

Neuheit (N)	Ja: Ansprüche	1-10
	Nein: Ansprüche	
Erfinderische Tätigkeit (ET)	Ja: Ansprüche	1-10
	Nein: Ansprüche	
Gewerbliche Anwendbarkeit (GA)	Ja: Ansprüche	1-10
	Nein: Ansprüche	

**2. Unterlagen und Erklärungen
siehe Beiblatt**

VI. Bestimmte angeführte Unterlagen

1. Bestimmte veröffentlichte Unterlagen (Regel 70.10)

und / oder

2. Nicht-schriftliche Offenbarungen (Regel 70.9)

siehe Beiblatt

VIII. Bestimmte Bemerkungen zur internationalen Anmeldung

Zur Klarheit der Patentansprüche, der Beschreibung und der Zeichnungen oder zu der Frage, ob die Ansprüche in vollem Umfang durch die Beschreibung gestützt werden, ist folgendes zu bemerken:

siehe Beiblatt

V

Die vorliegende Anmeldung erfüllt die Erfordernisse der Artikel 33(2) und (3) PCT, weil der Gegenstand der Ansprüche 1-10 im Hinblick auf den zitierten Stand der Technik neu und erfinderisch erscheint.

Keines der zitierten Dokumente erwähnt das Verfahren zur Herstellung solcher Copolymere aus Kohlenmonoxid und einer olefinisch ungesättigten Verbindung in wässrigem Medium in Gegenwart der beschriebenen Katalysatoren, Lösungsvermittler (Emulgatoren) und Hydroxyverbindungen. Dieses Ergebnis ist auch vom zitierten Stand der Technik nicht ableitbar.

VI

Ogleich das Dokument WO-A-00/01756 (veröffentlicht am 13.01.2001 und mit Prioritätsdatum von 02.07.1998) kein Stand der Technik im Sinne der Regel 64.1 (b) PCT ist, dürfte dieses Dokument alle Merkmale der vorliegenden Ansprüche 1-4, 6-8 und 10 offenbaren, denn auch Wasser kann sowohl als ein "Lösungsvermittler" als auch eine "Hydroxyverbindung" betrachtet werden.

VIII

Der in den Ansprüchen 1-4 und 10 benutzte Begriff "Lösungsvermittler" hat eine sehr breite Bedeutung, besonders im Hinblick auf das, was unter Punkt VI gesagt wurde (Artikel 6 PCT).

Dasselbe gilt für den Begriff "Hydroxyverbindung" in Ansprüchen 1-4.